This section contains information about Durable Medical Equipment (DME). For general policy information, refer to the *Durable Medical Equipment (DME): An Overview* section in this manual.

### **GENERAL INFORMATION**

### **DME Group**

This DME section includes the following items:

- Ambulation Devices
  - Gait Trainer
- Bathroom Equipment
- · Hospital Beds and Accessories
- Patient Lifts and Standing Frames
  - Standing Systems and Standing Frames
  - Stairway Chairlifts
- Patient Transfer Systems
  - Pneumatic Compressors
  - Lymphedema Pumps
  - Segmental Pneumatic
- Miscellaneous Equipment, Accessories and Supplies
  - Blood Glucose Monitors
  - Blood Pressure
  - Breast Feeding
  - Haberman Feeder
  - Helmets and Helmet Interface Replacement
  - Negative Pressure Wound Therapy
  - Non-Invasive Osteogenesis
  - Non-Spinal Electrical Device
  - Pulsed Irrigation Enhanced Evacuation (PIEE)
  - Positioning Seat
  - Ramps, Portable
  - Spinal Electrical Device
  - Ultrasound Device
  - Wearable Cardiac Defibrillator
  - Supplies and Accessories

Refer to the appropriate section in this manual for details about the following DME:

- Infusion equipment
- · Oxygen and respiratory equipment
- Speech generating devices/communication devices
- Therapeutic anti-decubitus mattresses and bed products
- Wheelchairs and wheelchair accessories

Refer to the *Durable Medical Equipment (DME): Billing Codes and Reimbursement Rates* section of this manual for other items and codes reimbursable by Medi-Cal.

### TREATMENT AUTHORIZATION REQUESTS

#### Where to Submit TARs

Treatment Authorization Requests (TARs) for codes within these groups must be submitted to the San Francisco Medi-Cal Field Office. See the TAR Field Office Addresses section in this manual for details.

### **Documentation**

Unless otherwise specifically noted, all TARs for the purchase, rental, repair or maintenance for items within the DME group must have the following documentation attached:

- Completed 50-1 TAR form
- A copy of the signed physician prescription or a completed and signed DHS 6181 form (Certificate of Medical Necessity for All Durable Medical Equipment [Except Wheelchairs and Scooters])
- For listed items: Specific medical justification for each item is requested, using either the DHS 6181 form or additional medical documentation, such as physician's notes or therapist documentation relevant to the request.

#### **NON-WHEELCHAIR DME**

## Reimbursement for Listed Codes

In compliance with *Welfare and Institutions Code* (W&I Code), Section 14105.48, claims for DME, with no specified maximum allowable rate ("By Report"), <u>except</u> wheelchairs and wheelchair accessories, is the least of the following:

- The amount billed pursuant to California Code of Regulations (CCR), Title 22, Section 51008.1, or
- An amount that does not exceed 80 percent of the lowest maximum allowance for California, established by the federal Medicare program for the same or similar item, or
- · A contracted rate

For more information regarding the maximum allowable DME purchase billing amounts, refer to "Net Purchase Price" in the *Durable Medical Equipment (DME): An Overview* section.

# Reimbursement for "By Report" Codes

In compliance with W&I Code, Section 14105.48, reimbursement for all DME, with no specified maximum allowable rate ("By Report"), <a href="maximum">except</a> wheelchairs and wheelchair accessories, is the least of the following:

- The amount billed pursuant to CCR, Title 22, Section 51008.1
- 80 percent of the Manufacturer's Suggested Retail Price
  (MSRP). For dates of service on or after September 1, 2006,
  MSRP must be an amount that was published by the
  manufacturer prior to June 1, 2006. If the item was not
  available prior to June 1, 2006, the date of availability must be
  documented in the Reserved for Local Use field (Box 19) of the
  claim and the catalog page that initially published the item and
  the MSRP must be attached. For dates of service prior to
  September 1, 2006, MSRP must be published prior to
  August 1, 2003.
- The manufacturer's purchase invoice amount, plus a 67 percent markup

For more information regarding the maximum allowable DME purchase billing amounts, refer to "Net Purchase Price" in the *Durable Medical Equipment (DME): An Overview* section.

# **Documentation Requirements**

Non-wheelchair DME codes billed with no specified maximum allowable rate ("By Report") require the following information:

- For dates of service on or after September 1, 2006, manufacturer's purchase invoice and the MSRP (a catalog page) published prior to June 1, 2006. For dates of service prior to September 1, 2006, MSRP must be published prior to August 1, 2003. (If the item was not available prior to June 1, 2006, attach a manufacturer's purchase invoice and the catalog page that initially published the item and the MSRP, and complete the Reserved for Local Use field (Box 19) with the date of availability.)
- Item description
- Manufacturer name
- Model number
- · Catalog number
- The reason a listed code was not used

Providers who are also manufacturers of DME items need only submit the MSRP with claims for items they manufacture. Refer to "Documentation Requirements for Provider/Manufacturer" in the *Durable Medical Equipment (DME): An Overview* section for information.

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### MSRP Documentation

The only acceptable MSRP documentation is a hard copy catalog page or a hard copy of an electronic catalog page as follows:

- For dates of service on or after September 1, 2006, the
  manufacturer's price list and/or order form dated prior to
  June 1, 2006. For dates of service prior to September 1, 2006,
  the manufacturer's price list and/or order form dated prior to
  August 1, 2003.
- The applicable publish date of the manufacturer's catalog page that includes a description of the item, the manufacturer's name, the model number/catalog number of the item (if available) and the MSRP.

If the item was not available prior to June 1, 2006, (or August 1, 2003) providers must submit the:

- Date of availability in the Reserved for Local Use field (Box 19) of the CMS-1500 claim
- Manufacturer's price list and/or order form or catalog page that initially published the item
- MSRP

## Claim Denials

Claims that do not include <u>all</u> of the required documentation will be denied.

# Non-Wheelchair Rentals Subsequently Rented to Recipients

Claims for reimbursement of non-wheelchair items that DME providers rent from a manufacturer and subsequently rent to recipients must be submitted with the appropriate non-wheelchair item HCPCS code and modifier RR. Both the manufacturer's rental invoice and a catalog page with the MSRP must be submitted with the claim.

## **Pricing Discounts**

Only discounts known to the provider at the time the claim is submitted will be used when pricing claims.

#### **AMBULATION DEVICES**

#### **Gait Trainer**

Definition

A gait trainer is a mobile external, fixed base of support that also provides either extensive trunk/postural supports and/or pelvic stability supports in order to allow mobility

Coverage

Coverage of gait trainer devices is limited to those recipients meeting the medical necessity criteria.

Medical Necessity

A copy of the written prescription signed by a licensed practitioner functioning within the scope of his/her practice must be submitted to the Medi-Cal office. Adequate documentation in the medical records for the recipient must clearly indicate the need for a gait trainer device based on the recipient's medical condition.

#### TAR Requirement

A *Treatment Authorization Request* (TAR) must be submitted by the recipient's provider to the appropriate Medi-Cal field office. A copy of the written prescription must accompany the TAR. Adequate documentation in the recipient's medical records that accompany the TAR must include the following:

- Evaluation must be done by a licensed physical therapist.
- Recipient must be able to use the gait trainer in a purposeful manner.
- Recipient must be able to partially bear weight and advance lower extremities.
- Recipient requires greater structural and balance assistance than provided by a walker.
- Recipient must have satisfactory head control.
- Recipient does not have any other form of self-initiated mobility.

The following are other related criteria that must be taken into consideration for gait training devices:

- Recipient may need attendant assistance to be positioned in a gait training device.
- Recipient must have support and willingness to comply with safety considerations and any self-directed programs.
- Recipient may need supervision when using the device.
- Recipient may require ample space for use of the equipment.
- Recipient's parents or guardians (for pediatric recipients) must demonstrate that they are compliant with all considerations in a prescribed home-walking program.
- Recipient's upper extremity weight-bearing ability, joint stability, and ability to maneuver must be given consideration in choosing a possible gait trainer type.

Gait trainers and walkers serve different purposes for the recipients. Submitted TARs will be reviewed based on medical necessity.

**HCPCS Codes** 

Providers must bill for gait trainer devices with HCPCS codes E8000 (gait trainer, pediatric size, posterior support, includes all accessories and components), E8001 (...upright support, includes all accessories and components) and E8002 (...anterior support, includes all accessories and components).

## **BATHROOM EQUIPMENT**

# Coverage

Bathroom equipment such as rails, seats, stools, benches, and shower hoses and accessories are not covered by Medicare.

Providers may bill Medi-Cal for bathroom equipment without having to first obtain a denial from Medicare. For more information, see the *Medicare Non-Covered Services: HCPCS Codes* section in this manual.

# **Commode Chairs**

HCPCS codes E0170 (commode chair with integrated seat lift mechanism, electric, any type) and E0171 (...non-electric) must include documentation on the TAR that the patient has a neuromuscular dysfunction or disease, or arthropathy of the hips and/or knees. E0170 and E0171 are not separately reimbursable in the same month of service.

#### **HOSPITAL BEDS AND ACCESSORIES**

### **Billing Restriction**

HCPCS codes E0271 (mattress, inner spring), E0272 (mattress, foam rubber), E0305 (bedside rails; half length) and E0310 (bedside rails; full length) are not reimbursable if billed with code E0303 (hospital bed, heavy duty, extra wide, with weight capacity greater than 350 pounds but less than or equal to 600 pounds, with any type side rails, with mattress), code E0304 (hospital bed, extra heavy duty, extra wide, with weight capacity greater than 600 pounds, with any type side rails, with mattress), code E0328 (hospital bed, pediatric, manual, 360 degree side enclosures, top of headboard, footboard, and side rails up to 24 in. above the spring, includes mattress) or code E0329 (hospital bed, pediatric, electric or semi-electric, 360 degree side enclosures, top of headboard, footboard, and side rails up to 24 in. above the spring, includes mattress). If any combination of the mattress and/or bedrail codes is billed separately, no more than the allowed amount for bed codes E0303, E0304, E0328 or E0329 will be paid.

For pricing information, see "Hospital Beds and Accessories" in the Durable Medical Equipment (DME): Billing Codes and Reimbursement Rates section of this manual.

**Note:** HCPCS codes E0303 and E0304 are semi-electric, as are all heavy duty beds. Semi-electric beds electronically control the head and knee sections and manually adjust the height.

### **Pediatric Crib**

HCPCS code E0316 (safety enclosure frame/canopy for use with hospital bed, any type) is not separately reimbursable to any provider if billed for the same recipient with HCPCS code E0300 (pediatric crib, hospital grade, fully enclosed).

#### Criteria for Pediatric Beds

Most pediatric medical conditions do not require specialized home furnishings as prescribed medical treatment. It is reasonable to expect parents or legal caregivers of infants and children to provide an appropriate bed and bed care items necessary for comfort and positioning. However, a hospital or specialized bed and related accessories may be medically necessary for pediatric recipients when the nature and severity of their illness, injury, or disease meets all of the following medical criteria:

- The hospital bed is necessary to treat the medical condition as documented in the medical record.
- The hospital bed is expected to produce a positive medical outcome which would not occur without the bed, or will prevent complications or worsening of the medical condition for which it is prescribed.

- The desired medical benefit is not attainable by use of an ordinary bed.
- An ordinary bed cannot be modified or adapted by commercially available items to meet the medical need.

Enclosed cribs or enclosed pediatric beds may be medically necessary for recipients with diagnosis of developmental delay when the nature and severity of their illness, injury, or disease meets all of the following medical criteria:

- The behavioral necessity for an enclosed bed is documented and described in the medical record.
- There is clinical documentation that underlying behavioral issues have been proactively addressed with appropriate behavioral interventions and modification without success.
- Other less restrictive forms of bed restraint/accommodations have been employed without adequate success (such as increased caregiver monitoring, alarm systems, padding bedrails or placing mattress on the floor).
- An ordinary bed cannot be modified or adapted by commercially available items to meet the child's needs.
- There is no other appropriate and reasonably feasible alternative method for providing safe bed/sleep care.
- The request for the enclosed bed is not for caregiver convenience or due to lack of caregiver monitoring of recipient's safety.

California Children's Services Program Clients Requests for hospital beds and accessories for children case managed by California Children's Services (CCS) are reviewed by CCS for medical necessity for treatment of a CCS-eligible medical condition per *California Code of Regulations*, Title 22, Sections 41515.1 – 41518.9.

# Adult Hospital Beds and Accessories

Hospital beds and accessories are covered for recipients who meet medical necessity criteria. The medical records for the recipient must clearly reflect the medical necessity. Some examples of hospital bed accessories are: trapeze equipment, bed cradle, side rails and safety enclosures.

# **Types of Hospital Beds**

Following are the different types of hospital beds:

- · Fixed-height
- Variable-height
- · Semi-electric
- Heavy-duty extra-wide
- Extra heavy-duty
- Total electric

## **Coverage Criteria for Hospital Beds**

Fixed Height

Recipient must meet all of the following criteria for fixed height hospital beds:

- Recipient's positioning of body is not feasible in non-hospital beds.
- Recipient needs promotion of body alignment to prevent contractures in a patient with history of contractures or a documented medical condition that causes risks of contractures. Recipient also needs alleviation of pain and avoidance of respiratory infections with a documented history of such pain and infection related to positioning.
- Recipient needs elevation of the head of the bed more than 30 degrees due to certain medical conditions such as congestive heart failure (CHF), chronic obstructive pulmonary disease (COPD) or documented history of aspiration.
- Recipient needs use of special attachments or traction equipment.

**Note:** The hospital bed is not covered if elevation of the head/upper body is less than 30 degrees. Pillows and wedges must have been ruled out as an option.

Variable Height

The following criteria must be met for variable-height hospital beds:

- Recipient must meet the coverage criteria for fixed-height hospital bed, and
- Recipient requires height adjustment to transfer to chair, transfer to wheelchair, or get up to a standing position.

# Semi-Electric

Following are the coverage criteria for semi-electric hospital beds:

- Recipient must meet the coverage criteria for fixed-height hospital bed, and
- · Recipient requires frequent body position change, and/or
- Recipient requires immediate body position change.

# Heavy-Duty Extra-Wide

Following are the coverage criteria for heavy-duty extra-wide hospital beds:

- Recipient must meet the coverage criteria for fixed height hospital bed, <u>and</u>
- Recipient's weight is 351-600 lbs.

# Extra Heavy-Duty

Following are the criteria that must be met for extra heavy-duty hospital beds:

- Recipient must meet the coverage criteria for fixed-height hospital bed, and
- Recipient's weight exceeds 600 lbs.

## **Total Electric**

This item is mostly for convenience purposes and is not a Medi-Cal benefit.

# Certification of Medical Necessity

Medical necessity must be clearly documented by the licensed practitioner. A signed prescription by the licensed practitioner must accompany the TAR for the hospital bed. Clinical documentation must describe the medical condition, severity and frequency of symptoms that necessitate a hospital bed. The therapeutic outcome expected to be achieved with the use of the hospital bed, availability of a caregiver, and recipient's level of independence to operate the bed must also be included in the clinical documentation.

### PATIENT LIFTS AND STANDING FRAMES

# **Standing Systems and Standing Frames**

Standers and standing frames to allow wheelchair dependent patients to achieve a passive standing position are Medi-Cal benefits subject to authorization. The equipment is billed with HCPCS codes E0637 (combination sit to stand system, any size including pediatric, with seatlift feature, with or without wheels), E0638 (standing frame system, one position, any size including pediatric, with or without wheels), E0641 (standing frame system, multi-position, any size including pediatric, with or without wheels) or E0642 (standing frame system, mobile [dynamic stander], any size including pediatric).

## Medical Necessity

Standers and standing frames are considered medically necessary when there is documentation of the following:

- The device would allow the recipient to become more independent in one or more of the activities of daily living, and
- For a recipient with a pressure sore, the device would provide pressure relief/off-loading of the pressure sore that cannot be accomplished by other means, or
- Lower body strength is increased by maintaining a standing position for recipients with spastic quadriplegia or other neuromuscular conditions who are unable to rise from a seated to standing position without assistance and have some residual strength in the hips or legs, or
- Lower body strength is increased by maintaining a standing position for recipients with paraplegia and other neuromuscular conditions who are unable to rise from a seated to a standing position without assistance and have some residual strength in the hips or legs, and
- There is documentation that the recipient has tried the system through an ongoing outpatient therapy program and the physical therapist has witnessed the use of the system and recommends it.

Standers and standing frames are not considered medically necessary for recipients with complete paralysis of the hips and legs, such that lower body range of motion is not improved or maintained by the standing position, or if using the stander/frame would create an unsafe situation for the recipient.

# Prescribing Physician

When ordering standing equipment billed with codes E0637, E0638, E0641 or E0642, the prescribing physician must provide medical documentation that the recipient has had sufficient training with the system and does not have a fracture risk or does not develop vertigo or become nauseous by standing. The prescribing physician must also document that the recipient is willing and able to stand and that there are suitable facilities and assistance available (when needed) in the recipient's home for standing.

## TAR Requirements

A TAR may be authorized only for those recipients who have had an adequate case management assessment of their overall needs for ambulation, positional changes and other essential activities of daily living, including an onsite evaluation as necessary.

TARs requesting authorization of HCPCS codes E0637, E0638, E0641 or E0642 must include the following information.

- Diagnosis, age, height and weight, or other information regarding size
- Description of functions (sitting ability, standing ability, mobility)
- Description of transfers, functional goals, current program directed toward functional goals
- Daily activities, relevant impairment (range of motion, bowel/bladder/intestinal function, history of fractures or risk for bone density issues, respiratory status)

A three-month rental period is mandatory before purchase of any stander/standing frame unless the recipient has participated in a community program of standing three to four times per week, for at least three months.

Additionally, the TAR must provide answers to the following questions:

- What is the recipient's history of standing or efforts to stand?
- What is the recipient's current standing program? Does the recipient stand in any other setting (school, work setting, etc.)?
- Is the recipient able to stand by any method other than a stander (against furniture, with assist of caregiver, with a strap or support, with a walker, etc.)?
- How is the use of a stander related to the functional goals for this recipient?
- What specific activities for this recipient require a stander?
- Is there a home program or therapy program that requires regular use of a stander?
- Has this recipient experienced a trial of the proposed stander or any other stander and what were the results?

- What other standing devices were considered, and why were they rejected?
- What other less costly alternatives were considered, and why
  were they rejected (other approaches to identified needs –
  range of motion, stretching, splints, respiratory activities, other
  methods of weight-bearing, etc.)?

#### PATIENT TRANSFER SYSTEMS

# Multi-positional Patient Transfer Systems

HCPCS code E1035 (multi-positional patient transfer system, with integrated seat, operated by care giver, patient weight capacity up to and including 300 lbs.)

HCPCS code E1036 (multi-positional patient transfer system, extra-wide, with integrated seat, operated by care giver, patient weight capacity greater than 300 lbs.)

For pricing information, see "WHEELCHAIRS, MODIFICATIONS AND ACCESSORIES, Transport Chairs" in the *Durable Medical Equipment* (DME): Billing Codes and Reimbursement Rates section of this manual. These codes are nontaxable.

Code E1036 requires a Treatment Authorization Request (TAR).

HCPCS codes E1035 and E1036 are not separately payable within the same month as code E0240 (bath/shower chair, with or without wheels, any size).

The frequency limit for codes E1035 and E1036 is once in five years.

# **Stairway Chairlifts**

A stairway chairlift is a Medi-Cal benefit, subject to authorization. Providers must bill using HCPCS code E1399.

## **TAR Requirements**

Each TAR will be reviewed on a case-by-case basis. Medical necessity, cost considerations, less costly options available and the ability of the recipient or caregiver to independently and safely operate the stairway chairlift will be taken into consideration.

# **Required Documentation**

The following documentation must accompany the TAR:

- A description of all rooms available to the recipient on the residence level used by the recipient
- A description of other rooms on other levels of the residence that the recipient must access for activities of daily living

- The physician's prescription
- An explanation of why the stairway chairlift is medically necessary for the recipient, including which less costly options have been tried or considered, and why these options did not meet the medical needs of the recipient

Adjudication of TARs for stairway chairlifts is conducted by the San Francisco Medi-Cal Field Office.

Reimbursement

Reimbursement for code E1399 is "By Report."

#### PNEUMATIC COMPRESSORS

# Lymphedema Pumps/ Pneumatic Compression Devices

Coverage of lymphedema pumps/pneumatic compression devices is limited to mastectomy patients and patients with upper and lower extremity conditions. One of the following ICD-9-CM diagnosis codes is required on the TAR, but is not required on the claim: 457.0, 457.1 or 757.0.

All lymphedema pumps/compression devices (HCPCS codes E0650, E0651, E0655 – E0657, E0660, E0665 – E0669, E0671 – E0673) require authorization. They must be prescribed by a licensed practitioner within the scope of his/her practice and are subject to appropriate physician oversight. The ideal situation would be for these patients to be under case management. An initial 60-day trial rental may be authorized and must establish clinical effectiveness.

Lymphedema pumps and pneumatic compression devices are not covered when the following medical guidelines are not met or for other indications such as venous insufficiency. Pumps or sequential pneumatic compression devices are contraindicated in the presence of active infection or deep vein thrombosis in the affected limb.

#### Criteria

Lymphedema pumps/compression devices are subject to the following criteria:

- The recipient has a confirmed diagnosis of primary or secondary lymphedema, and
- Lymphedema has been shown to be associated with functional impairment of the recipient.

- Conservative medical therapies, such as elevation of the affected limb, exercise, massage and/or use of an appropriate compression bandage system or compression garment, have been tried for at least 30 days and failed to reduce prolonged lymphedema, and
- The recipient has demonstrated compliance with the past recommended medical treatment(s).

Lymphedema pumps and pneumatic compression devices may be purchased (modifier NU) or rented (modifier RR). Purchase or continued rental may be authorized when there is documented effectiveness of the pump (a decrease in edema is documented by pre- and post-treatment measurements and/or documentation of functional improvement).

# Segmental Pneumatic Appliances

Reimbursement for HCPCS codes E0656 (segmental pneumatic appliance, trunk) and E0657 (segmental pneumatic appliance, chest) requires authorization and must be billed using modifier NU for purchase, RR for rental or RB for repair/replacement. The TAR must include one of the following:

ICD-9-CM	
Diagnosis Code	<u>Description</u>
457.0	Postmastectomy lymphedema syndrome
457.1	Other lymphedema
757.0	Hereditary edema of legs

Codes E0656 and E0657 are restricted to once-in-a-lifetime reimbursement per recipient, any provider.

### MISCELLANEOUS EQUIPMENT, ACCESSORIES AND SUPPLIES

### **Blood Glucose Monitors**

Blood glucose monitors (glucometers), with or without special features, may be prescribed for the purpose of monitoring a recipient's blood glucose levels at home when the recipient has any of the following conditions:

- Type I insulin-dependent diabetes
- Type II non-insulin-dependent diabetes
- Diabetes Mellitus complicating pregnancy
- · Gestational diabetes

Home blood glucose monitors are billed with HCPCS code E0607. Blood glucose monitors with special features (for example, integrated voice synthesizers) are billed with HCPCS codes E2100 or E2101. **Documentation Requirements** 

Claims for any blood glucose monitor must include the ICD-9-CM diagnosis (including all relevant digits) related to the type of diabetes for which the instrument is being prescribed. Claims for HCPCS code E0607 must contain documentation that the recipient or caregiver is competent to monitor the equipment <u>and</u> that the device is designed for home rather than clinical use. Claims for HCPCS codes E2100 or E2101 must be billed "By Report."

Authorization

Authorization is always required for glucometers with special features (HCPCS codes E2100 and E2101). Authorization is required for code E0607 only when the cost exceeds the established TAR threshold limits for rental or purchase of Durable Medical Equipment (DME). The TAR must contain the following documentation:

- Diagnosis of Type I diabetes (ICD-9-CM 249.00 249.91, 250.00 250.93), Type II diabetes (249.00 249.91, 250.00 250.93), Diabetes Mellitus complicating pregnancy (648.00 648.04), or gestational diabetes (648.80 648.84) with intent to monitor blood glucose at home, and
- Written statement that the requested glucometer is the least costly item available that will meet the recipient's medical needs, and
- For codes E2100 and E2101, written explanation of the severity of the impairment justifying a special feature for the effective use of the equipment, and
- For codes E2100 and E2101, written statement that the
  recipient requesting a glucometer with special features is
  capable of using the equipment in the home setting, and is not
  dependent upon a caregiver for blood glucose testing. (If the
  recipient is dependent upon a caregiver, the caregiver's need
  for any requested special features must be justified.)

Supplies

Glucometer test strips, lancets and other monitoring supplies are billed using specific medical supply codes. For information about specific codes, refer to the *Medical Supplies List* sections in the appropriate Part 2 manual.

Blood Pressure Equipment Blood pressure equipment (HCPCS codes A4660, A4663 and A4670) is reimbursable only for documented malignant hypertension or End Stage Renal Disease. Claims must be submitted with one of the following ICD-9-CM diagnosis codes:

401.0 - 405.9, 585.1 - 586

Breastfeeding: Lactation		Lactation management aids include breast pumps and breast pump		
Management Aids	kits that may be purchased or rented if medically necessary. Follow			
	these guidelines when billing for breast pumps and breast pump kits.			
	HCPCS Code	<u>ltem</u>	<u>TAR</u>	
	E0602	Breast pump, manual, any style	Required if the cumulative cost within the calendar month for the purchase of DME items within a group exceeds \$100	
	E0603	Breast pump, electric (AC and/or DC), any type. This is also known as a personal grade (single-user) electric breast pump.	Required if the cumulative cost within the calendar month for the purchase of DME items within a group exceeds \$100	
	E0604	Breast pump, hospital grade, electric (AC and/or DC), any type. This is also known as a hospital grade (multi-user) electric breast pump.	Required if the cumulative cost within a 15-month period for breast pump, DME items within a group exceeds \$164	
	<b>Note:</b> Code E0602 may be used to bill either a manual breast pump or a breast pump kit.			
Hospital Grade (Multi-User) Electric Breast Pumps	Hospital grade (multi-user) electric breast pumps (HCPCS code E0604) are covered for daily rental only. If there are no other relevant rentals, a TAR is not required until the rental amount exceeds \$164 in a 15-month period.			
Documentation When TAR is Required	A TAR must be accompanied by documentation establishing that the item is medically necessary in either of the two following situations:			

 If direct nursing at the breast <u>is</u> established during the neonatal period (the period immediately following birth and continuing through the first 28 days of life) and nursing is interrupted, medical necessity for code E0604 is defined as the existence of any of the following medical conditions:

- The mother has a medical condition that requires treatment of her breast milk before infant feeding; or
- The mother is receiving chemotherapy or other therapy with pharmaceutical agents that render her breast milk unsuitable for infant feeding; or
- The infant developed a medical condition or requires hospitalization that precludes direct nursing at the breast on a regular basis.
- If direct nursing at the breast is not established during the neonatal period, medical necessity for code E0604 is defined as the existence of any of the following medical conditions:
  - Any maternal medical condition that precludes direct nursing at the breast; or
  - The infant has a congenital or acquired neuromotor or oral dysfunction that precludes effective direct nursing at the breast; or
  - The infant has a congenital or acquired condition that precludes effective direct nursing at the breast; or
  - The infant continues to be hospitalized and the mother is no longer an impatient.

# TAR Requirements

TARs for the rental or purchase of electric pumps must include the following:

- A complete, detailed description of the medical necessity (see situations listed above) for the requested equipment.
- An explanation of why an electric pump or other specialized equipment must be used instead of a less expensive manual device.

When a TAR is required, it must be accompanied by a prescription signed by a licensed health care practitioner within their scope of practice. The name and birth date of the infant being breastfed must be written on the TAR or the prescription.

TARs are submitted to the San Francisco Medi-Cal Field Office. See the *TAR Field Office Addresses* section in this manual for additional information.

Durable Medical Equipment (DME) coverage is limited by the *California Code of Regulations* (CCR), Title 22, Section 51321, to the lowest cost item that meets the patient's medical needs. Once the cumulative rental of a hospital grade (multi-user) electric breast pump exceeds the pump's maximal allowable purchase price, no further rental shall be authorized and the item shall be deemed to have been purchased.

## Haberman Feeder: HCPCS Code S8265

HCPCS code S8265 (Haberman Feeder) is reimbursable with the following restrictions:

- Maximum age is 1 year old
- Frequency limit
- Diagnosis code is limited to ICD-9-CM codes 352.6,
   749.00 749.25 or 779.31.

#### **Helmets: Prefabricated**

Prefabricated helmets (HCPCS codes A8000 and A8001) and replacement interface (HCPCS code A8004) are reimbursable to DME providers (see the following policy for interface replacement code A8004). The prefabricated helmets are taxable items and must be billed as a purchase (modifier NU) or repair (modifier RB) only. The helmets are not to be rented (modifier RR is not allowed). Claims for replacement interfacing code A8004 billed with modifier RB require documentation that the patient owns the helmet.

# Helmet Interface Replacement HCPCS Code A8004

Replacement interface code A8004 must be billed as a repair/replacement (modifier RB). This item is not rented (modifier RR is not allowed). Claims for code A8004 must include documentation that the patient owns the helmet. Code A8004 is a taxable item.

# Negative Pressure Wound Therapy (NPWT) Devices

Negative Pressure Wound Therapy (NPWT) devices include pumps and wound care sets. They are typically used after other appropriate wound treatment modalities have failed to heal skin wounds or ulcers. NPWT devices and supplies are billed with the following codes:

HCPCS <u>Code</u>	<u>Description</u>	<u>Limitations</u>
A6550	Wound care set, for negative pressure wound therapy electrical pump, includes all supplies and accessories	Reimbursable for purchase only. Frequency is limited to 15 per month (all may be dispensed on the same date of service).
A7000	Canister, disposable, used with suction pump, each	Reimbursable for purchase only. Frequency is limited to 10 per month (all may be dispensed on the same date of service).
A7001	Canister, non-disposable, used with suction pump, each	Reimbursable for purchase only. Frequency is limited to 1 in 6 months.
E2402	Negative pressure wound therapy electrical pump, stationary or portable	Reimbursable for daily rental only. Must be capable of accommodating more than one wound dressing set, for multiple wounds on a patient.

TAR Requirement

NPWT pumps and supplies require a TAR. The initial TAR for the pump will be granted for a period of no more than 30 days. Reauthorization TARs may be granted in increments of up to 30 days. Only one pump may be authorized for the 120-day period. Coverage beyond 120 days will be given individual consideration based upon required additional documentation.

## **Documentation Requirements**

The following documentation must be submitted with each TAR:

- Written prescription form signed by a licensed practitioner functioning within the scope of his or her practice that details medical necessity of the NPWT, including all of the following:
  - Summary of the patient's medical condition
  - Relevant wound history, including prior treatments
  - Documentation of the medical condition necessitating the NPWT
  - Duration of time the patient is expected to require the NPWT
- Documentation of the treatment plan, including all of the following:
  - A detailed description of each wound, including precise measurements, and description of exudates, necrotic tissue and granulation tissue
  - Wound care plan (must document appropriate wound care is being provided)
  - Nursing care plan (must document appropriate nursing care is being provided)
  - Concurrent issues relevant to wound therapy (debridement, nutritional status, support surfaces in use, positioning and incontinence control)

Documentation, at least every 30 calendar days, of quantitative wound characteristics, including wound length, width and depth.

#### Contraindications

NPWT coverage will be denied as not medically necessary if any of the following contraindications are present:

- Necrotic tissue with eschar in the wound
- Untreated osteomyelitis within the vicinity of the wound
- · Malignancy in the wound

# Non-Invasive Osteogenesis

Authorization is required for the following osteogenesis stimulator devices. Additionally, a dated order for the osteogenesis stimulator and related supply items, signed by the treating physician, must be kept on file by the supplier of the equipment.

HCPCS Code	<u>Description</u>
E0747	Osteogenesis stimulator; electrical, non-invasive, other than spinal applications
E0748	spinal applications
E0760	Osteogenesis stimulator, low intensity ultrasound, non-invasive

All claims for an osteogenesis stimulator and related supplies must include an ICD-9-CM code that describes the condition requiring the device. For nonunion fractures, the claim must include both the ICD-9-CM code 733.82 (nonunion of fracture) and the specific ICD-9-CM code for the fracture site.

Even though osteogenesis stimulators are returned and reused following completion of treatment, they must be authorized as a purchase item and billed with modifier NU, regardless of the period of use. These items may not be rented. The purchase-only reimbursement is all-inclusive of the following:

- All accessories necessary to use the unit (for example, electrodes, wires, gel, cables, etc.)
- Patient education on the proper use and care of the equipment
- Routine servicing and all necessary repairs or replacement to make the unit functional

## Non-Spinal, Electrical Device

Non-spinal electrical osteogenesis stimulator devices are billed with HCPCS code E0747. These devices are composed of two basic parts: the coils that wrap around the patient's cast and the pulse generator that produces an electric current. The devices are built based on measurements specified by a recipient's physician.

Non-spinal electrical osteogenesis stimulator devices are covered for nonunion fractures only if the following criteria are met:

- Nonunion of a long bone fracture, defined as radiographic evidence that fracture healing has ceased.
- Six months or more have passed since the fracture.
- Bone X-rays over the last three months show no sign of continued healing.
- Six months or more have passed since the alternative treatment was initiated.
- The fracture gap is one centimeter or less.
- The patient can be adequately immobilized and is able to comply with non-weight bearing.
- For infantile (congenital) pseudoarthroses (ICD-9-CM code 755.8).
- There is evidence of skeletal maturity or the patient is 20 years of age or older.

**Note:** Nonunion of the long bone must be documented by a minimum of two sets of radiographs obtained prior to starting treatment with the osteogenesis stimulator, separated by a minimum of 90 days, each including multiple views of the fracture site, and with a written interpretation by a physician stating that there has been no clinically significant evidence of fracture healing between the two sets of films.

A non-spinal electrical osteogenesis stimulator will be denied as not medically necessary if none of the above criteria are met.

# Pulsed Irrigation Enhanced Evacuation (PIEE)

Pulsed Irrigation Enhanced Evacuation (PIEE) may be authorized for patients with neuropathic bowel due to underlying neurologic problems that dispose them to severe fecal impaction and who have failed all traditional and conservative attempts at bowel control.

Authorization

The PIEE equipment and supplies require authorization. They are billed with the following codes:

HCPCS Code Description

E0350 Control unit for electronic bowel

irrigation/evacuation system

E0352 Disposable pack (water reservoir bag,

speculum, valving mechanism and collection bag/box) for use with the electronic bowel

irrigation/evacuation system

The PIEE control unit (code E0350) includes one (1) battery charger, one (1) remote control assembly and PIEE cart or traveler and one (1) PIEE fill system. The therapy kit (code E0352) includes one (1) B-Valve circuit, two (2) containment bags, one (1) lubricating jelly, one (1) bed pad, one (1) tray liner-waste disposable bag and two (2) hose clamps. Each case of 15 kits contains two (2) replacement fill tubes and 15 adult inflatable cuffed speculums.

Related supplies other than the disposable pack are billed with code A9900 (miscellaneous DME supply, accessory, and/or service component of another HCPCS code).

Separate *Treatment Authorization Requests* (TARs) may be required for the approval of services related to PIEE and for the equipment and/or supplies.

The PIEE <u>device</u> will have an initial two-month trial of rental to provide documentation that long-term use will be medically necessary and effective. Following this two-month rental, a TAR must be submitted for the purchase of the PIEE device by the Medi-Cal program for permanent use by the recipient. The initial authorization for all <u>services</u> related to the PIEE procedure may be approved for no more than two months of treatment, through the last date of the month, to permit better utilization and ensure PIEE safety and efficacy for the recipient. Subsequent TARs for services related to the PIEE procedure and the treatment pack <u>supplies</u> may be approved for up to six-month increments, if there is medical documentation that indicates the recipient continues to require the procedure and that the procedure continues to provide effective evacuation for the recipient.

#### **Documentation Requirements**

The attending physician's documentation of the medical necessity for PIEE must include a complete history and physical exam; documentation of adequate caregiver support for training in the use of PIEE; and arrangement of skilled nursing home health visits to provide assistance and support for this service.

### **Positioning Seat**

HCPCS code T5001 (special orthotic positioning seat) requires authorization. Reimbursement is "By Report." Code T5001 must be billed with modifier NU (purchase), RR (rental) or RB (replacement of a part of DME furnished as part of a repair). Separate reimbursement for labor is allowed for the repair of patient-owned equipment. Claims billing code T5001 with modifier RB must document that the patient owns the positioning seat. This device is a taxable item

# Ramps, Portable

Claims for portable ramps must be billed with HCPCS code E1399 (durable medical equipment, miscellaneous). TARs for portable ramps submitted to the Medi-Cal field office must include medical justification and supporting documentation. Medical necessity documentation must be submitted by the recipient's health care provider. The following documentation must be submitted with each TAR:

- What the recipient has used for wheelchair access prior to this request
- The schematic drawing of the recipient's residence and measurements comparing all possible access sites for portable ramps
- Documentation demonstrating the door site selected as the least-costly access site for ramp use
- Documentation demonstrating the ramp type requested as the lowest cost item to meet the recipient's medical needs.
- The catalog pages for ramp type requested
- An invoice for the ramp
- Documentation demonstrating the ramp's intended use for occupied or unoccupied wheelchair
- Details of the mock-up trial for the requested ramp or similar ramp
- Documentation of the weight of the recipient, weight of the wheelchair, maximum rise of the ramp and maximum weight capacity of the ramp for power wheelchairs

Alterations or improvements to real property (for example, a non-portable wheelchair ramp to front door) are <u>not</u> covered. A portable wheelchair ramp is not home or vehicle modification. It should be considered an extension of the recipient's wheelchair and follows the recipient in his or her wheelchair to assist in accessibility to the community.

The following medical necessity criteria are taken into consideration for portable ramps:

- The recipient requires wheelchair (manual or power) for home and community mobility.
- The recipient requires access to vehicles for community mobility, and/or for accessibility in/out of the recipient's primary entrance into the home.
- The ramp can be used to load wheelchair into the back of a truck/van for transport.
- Onsite evaluation should be performed to ensure:
  - Caretaker can transport and set up ramp.
  - The chair can be driven or pushed by the caretaker up and down the ramp safely.

## Spinal, Electrical Device

Spinal electrical osteogenesis stimulator devices are billed with HCPCS code E0748. These devices are covered only if any of the following applies:

- Failed spinal fusion (pseudoarthrosis ICD-9-CM code V45.4, joint following fusion) and a minimum of nine months have elapsed since the last surgery, or
- Following a multi-level spinal fusion surgery involving three or more vertebrae (for example, L3-5, L4-S1, etc.), or
- Following spinal fusion surgery where there is a history of a previously failed spinal fusion at the same site, or
- The patient has one or more risk factors for high risk of spinal fusion failure such as smoking, obesity (BMI > 35), diabetes, renal disease, alcoholism, grade II or worse Spondylolisthesis, or other metabolic disease where bone healing is poor

**Note:** The device should be applied within 30 days as an adjunct to spinal fusion surgery. The patient should use the device for at least two hours per day and the treatment period continued for nine months (270 consecutive days). The device is programmed to cease operation at the end of 270 days.

# Low-Intensity Ultrasound Device

Non-invasive, low intensity ultrasound osteogenesis devices are billed with HCPCS code E0760 and are reimbursable at a "per treatment" rate. Providers must bill for purchase of the device even though it is returned to the manufacturer when the treatment is completed. This device is covered only if the following criteria are met:

- Nonunion of a fracture other than the skull or vertebrae in a skeletally mature person, documented by a minimum of two sets of radiographs obtained prior to starting treatment with the osteogenesis stimulator, separated by a minimum of 90 days each, including multiple views of the fracture site, and with a written interpretation by a physician stating that there has been no clinically significant evidence of fracture healing between the two set of radiographs, and
- The fracture is not tumor-related.
- Fresh (< 7 days), closed or grade I open, tibial diaphyseal fractures, or
- Fresh (< 7 days), closed fractures of the distal radius (Colles fracture.

An ultrasonic osteogenesis stimulator will be denied as not medically necessary if the criteria above are not met. An ultrasonic osteogenesis stimulator may not be used concurrently with other noninvasive stimulators.

# Wearable Cardiac Defibrillator (WCD) HCPCS code K0606

Code K0606 (automatic external defibrillator, with integrated electrocardiogram analysis, garment type), also known as a wearable cardiac defibrillator (WCD), is reimbursable as <u>rental-only</u>, <u>subject to</u> authorization.

Code K0606 is reimbursable as rental-only, on a monthly basis, and using modifier RR. Reimbursement for purchase, using modifier NU or repair/replacement modifier RB, is not allowed. The current monthly rental reimbursement rate established is \$1,814.56 per month.

The rental rate includes the following equipment: monitor/defibrillator, one garment (electrode belt), electrodes, two batteries, one charger, holster and modem. Separate reimbursement for this equipment, using non-benefit codes K0607 (replacement battery), K0608 (replacement garment), K0609 (replacement electrodes), or other current procedure codes is not allowed. In addition, code A9900 (miscellaneous DME supply, accessory, and/or service component of another HCPCS code) is not separately reimbursable with code K0606 if billed for any of the above equipment items, or for any other item related to a garment-type automatic external defibrillator.

For information regarding the authorization criteria for HCPCS code K0606, refer to "Wearable Cardiac Defibrillator (WCD) HCPCS code K0606" in the *Cardiology* section of the appropriate Part 2 provider manual.

Electrodes and Lead Wires: HCPCS Codes A4556 and A4557 HCPCS code A4556 (electrodes [e.g., apnea monitor], per pair) is reimbursable for electrodes for any appropriate patient-owned DME item, except transcutaneous electrical nerve stimulators (TENS) units.

HCPCS code A4557 (lead wires, [e.g., apnea monitor], per pair) is reimbursable for electrodes for any appropriate DME item, except TENS units.

Providers must document in the *Reserved for Local Use* field (Box 19) of the claim or on an attachment included with the claim that the equipment the lead wires/electrodes are for is owned by the patient.

Transcutaneous Electrical Nerve Stimulators (TENS): HCPCS Code A4595 HCPCS code A4595 (TENS supplies, 2 lead, per month) is reimbursable for patient-owned equipment only. TENS supplies include the following:

- Electrodes (any type)
- Lead wires (any type)
- Conductive paste or gel (if needed, depending on the electrode type)
- Tape or other adhesive (if needed, depending on the electrode type)

Providers must document in the *Reserved for Local Use* field (Box 19) of the claim or on an attachment included with the claim that the TENS equipment the leads are for is owned by the patient.

# Miscellaneous DME Supplies: HCPCS Code A9900

HCPCS code A9900 (miscellaneous DME supply, accessory, and/or service component of another HCPCS code) requires authorization and will only be authorized for patient-owned equipment. In addition, the following is required in the *Reserved for Local Use* field (Box 19) of the claim or on an attachment to the claim:

- Itemization of supplies, accessories or components
- · Documentation that the equipment is "patient owned"
- A statement next to each item billed with code A9900 indicating whether the item is "taxable" or "nontaxable"

**Exception:** The subject "Theratogs" must be entered in the *Reserved for Local Use* field (Box 19) instead of "patient owned" (as stated above) when billing for the Theratogs medical device.

# "By Report" Reimbursement

In compliance with *Welfare and Institutions Code*, Section 14105.48, reimbursement for supplies and accessories billed "By Report" are reimbursed at the lesser of:

- The amount billed (pursuant to *California Code of Regulations* [CCR], Title 22, Section 51008.1); or,
- The manufacturer's purchase invoice amount, plus a 23 percent markup.

For more information regarding the maximum allowable DME purchase billing amounts, refer to "Net Purchase Price" in the *Durable Medical Equipment (DME): An Overview* section.

## **UNLISTED EQUIPMENT**

## **Billing Requirements**

Unlisted equipment (excluding wheelchairs and wheelchair accessories) is billed with HCPCS code E1399 (DME, miscellaneous). Providers must itemize the equipment in the *Reserved for Local Use* field (Box 19) of the claim or on an attachment to the claim and state next to each item whether the item is "taxable" or "nontaxable."

If more than one item requires billing with code E1399, providers enter code E1399 on one claim line and indicate the total number of items being billed in the *Days or Units* field (Box 24G).

In addition, reimbursement for code E1399 requires attachment of a catalog page and invoice showing the items being billed. Providers must handwrite the claim line number (for example, "Line 1") next to each item being billed with code E1399.

**Reminder:** Items approved on separate TAR forms must be billed on separate claim forms.